

REMARKS

Applicant has reviewed and considered the Office Action mailed on June 6, 2003. Claim 1 is amended. Claims 1-3, 14, 15, 19, 28-31 are pending in this application.

Support for the amendment of claim 1 is provided by the specification at page 10, lines 5-
7.

§102a Rejection of the Claims

The Examiner has finally rejected claims 1-3, 14, 15, 19 and 28-31 as being anticipated by WO 97/19,676 (WO '676). The Examiner asserts that the intermediate mixture of example 4 of WO '676 anticipates Applicant's claims.

Applicant responds that his amendment of claim 1 overcomes this rejection. Applicant has now indicated in his claims that the minimum amount of polymer present in the polymer/solvent mixture is 0.5 grams per ml. This amount of polymer provides a minimum concentration of about 33% polymer in the composition. Note that the examples of the present application describe polymer/solvent concentrations of 40% and 37%. In contrast, the intermediate mixtures of WO '676's examples 4 and 9 have polymer/solvent concentrations of 10% and about 3% respectively. In other words, WO '676's examples contain significantly lower polymer concentrations than does Applicant's claimed composition.

As discussed in the prior amendment, the goal and achievement of WO'767 is the formation of uniform microcapsules having polymer shells. According to WO '676, a problem to be avoided is agglomeration of the microcapsules. With higher concentrations of polymer, agglomeration of the microcapsules and a lower encapsulation efficiency are obtained according to WO '676. See col. 5, lines 40-50 of the US equivalent of WO '676. Hence, one of skill would use polymer concentrations much lower than Applicant's claimed minimum if he were following the WO'676 teaching. This lower polymer concentration would expose the drug micelles to a higher concentration of organic solvent. Since the solvent is partially water soluble, there would be more of an opportunity for solvent to invade the micelles and cause denaturation of the peptide drug. This effect runs counter to the objects achieved by the present invention. See page 2, lines 1-12 of the application. Therefore, it is not within the skill of the art to employ

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116'

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such a higher concentration by following the teaching of WO '676.

For these reasons, Applicant submits that his claims, as amended, are distinguished from, and patentable over, WO'676. WO'676 leads one away from Applicant's invention because WO'676 teaches the use of low concentrations of polymer in organic solvent.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6939) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

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July 29, 2003

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of July, 2003.

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